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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/748,192

12/31/2003

Pei Kan

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BACON & THOMAS, PLLC

625 SLATERS LANE

FOURTH FLOOR

ALEXANDRIA, VA 22314-1176

EXAMINER

HOLLOMAN, NANNETTE

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/748,192	<b>Applicant(s)</b> KAN ET AL.	
	<b>Examiner</b> NANNETTE HOLLOMAN	<b>Art Unit</b> 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

Applicants' arguments, filed March 24, 2009, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

### ***Claim Rejections - 35 USC § 103 (Previous Rejection)***

Claims 1-14 were rejected under 35 U.S.C. 103(a) as being unpatentable over Sawhney (US Patent No. 6,632,457) in view of Jeong et al. (Macromolecules, Vol. 33, 2000, pp. 8317-8322). This rejection is maintained and is further applied to new claims 15-20.

### **Applicant's Arguments**

Applicant argues Sawhney does not teach "embedding" a bioactive substance with an oil phase carrier within temperature-sensitive thermogelling emulsion delivery system. Moreover, there is no recognition of temperature-sensitive thermogelling emulsion delivery system having an oil carrier embedding a bioactive substance in a

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soluble in oil, solid-in-oil, or water-in-oil form as recited in claims 8, 15 and 19.

Furthermore, the release mechanisms of the microspheres of Sawhney stand in contrast to that of the thermal-sensitive in situ forming hydrogel matrix of the present invention, wherein Sawhney would result in a 'burst release'.

In regards to Jeong et al., Applicant argues the reference does not disclose or suggest a temperature-sensitive thermogelling emulsion delivery system as claimed.

Applicant further argues the emulsion of the present invention has an unexpected and unique property (i.e., long-term sustained release) as compared to a hydrogel matrix.

### Examiner's Response

It appears Applicant is arguing the merits of the rejection based upon the disclosure of each reference alone. Jeong is used to disclose why one of ordinary skill in the art would want to modify the teaching of Sawhney and not as a stand alone reference as argued by Applicant. In regard to Sawhney, the reference discloses a controlled release delivery system where the drug release is controlled and sustained, while being free from "burst effects" (column 2, lines 41-44); wherein the drugs are "entrapped" (column 12, line 52) within the oil as for example, "soluble in oil" (column 12, lines 60-61), and the oil (hydrophobic) phase may be dispersed in a liquid solution to form an emulsion (column 13, lines 13-18), thereby, encompassing the limitation of "said oil carrier embeds said bioactive substance" of instant claim 1. In regard to Jeong not disclosing a temperature-sensitive thermogelling emulsion system, Jeong et al.

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disclose thermogelling polymers which are considered to meet the limitation of “temperature sensitive” as claimed, that gel in situ and are the basis of injectable systems that eliminate the need for surgical procedures and offers the advantage of the ability to form any desired implant shape providing the motivation to one of ordinary skill in the art to use such polymers in the composition of Sawhney.

In regard to Applicant’s unexpected and unique properties as compared to a hydrogel matrix, it is reasonable to conclude that similar results, such as long term sustained release, would occur when using the composition of Sawhney with the thermogelling polymers of Jeong because the combined teaching suggest the composition of the instant claims. Furthermore, Sawhney discloses the desire to extend release of therapeutic agents to several days, weeks, or even months with out the known hydrogel rapid release (column 9, lines 54-62). Therefore, the results do not appear to be unexpected based on the teachings of Sawhney in view of Jeong. Applicant’s comparison of examples 9 and 10 in the instant specification does not appear to be a proper comparison, as the results of FIG. 6A, p. 33 and FIG. 7A, p. 35 are not based on the same scale (Time (day)).

In regard to instant claim 18, it is being understood that similar properties, i.e. 3-10 fold greater sustained release of said bioactive substance compared to a hydrogel, would occur when using the composition of Sawhney with the thermogelling polymers of Jeong because the combined teaching suggest the composition of the instant claims.

***Conclusion***

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NANNETTE HOLLOMAN whose telephone number is (571) 270-5231. The examiner can normally be reached on Mon-Fri 800am-500pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/N. H./

Examiner, Art Unit 1612

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612